



PATENT

In re application of: **Antoni P. Tomsia**

Group No.: 1775

Examiner: Sperty

For: Glass/Ceramic Coatings for Implants

Mail Stop Appeal Briefs – Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION--37 C.F.R. § 41.37)**

1. Transmitted herewith is the revised APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on 28 February 2005.
2. STATUS OF APPLICANTS

This application is on behalf of a small entity.

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

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Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. § 1.8(a)

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37 C.F.R. § 1.10*

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TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____

Date:

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** Only the date of filing (' 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under ' 1.8 continues to be taken into account in determining timeliness. See ' 1.703(f). Consider "Express Mail Post Office to Addressee" (' 1.10) or facsimile transmission (' 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.*

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250.00 DA

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3. FEE FOR FILING APPEAL BRIEF

Pursuant to 37 C.F.R. § 41.20(b)(2), the fee for filing the Appeal Brief is:

small entity \$250.00

Appeal Brief fee due \$250.00

4. EXTENSION OF TERM

The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

Applicant petitions for an extension of time under 37 C.F.R. § 1.136 (fees: 37 C.F.R. § 1.17(a)(4) for 4 months:

Fee: \$795.00

If an additional extension of time is required, please consider this a petition therefor.

Extension fee due with this request \$795.00

5. TOTAL FEE DUE

The fee for filing the Appeal Brief and an extension for five months has already been secured, and the fee paid therefor of \$ 250 for the Appeal Brief is deducted from the total fee due.

The total fee due is:

Appeal brief fee (\$250.00)
Extension fee \$795.00

TOTAL FEE DUE \$795.00

6. FEE PAYMENT

Authorization is hereby made to charge the amount of \$795.00 to Deposit Account No. 120690.

A duplicate of this transmittal is attached.

7. FEE DEFICIENCY

If any additional extension and/or fee is required, charge Deposit Account No. 120690.

Date: 11/23/2005

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Practitioner's Docket No. IB-1627

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Antoni P. Tomsia

Application No.: 09/845,597

Filed: April 30, 2001

For: Glass/Ceramic Coatings for Implants

Group No.: 1771

Examiner: Sperty

**Commissioner for Patents
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Alexandria, VA 22313-1450**

ATTENTION: Board of Patent Appeals and Interferences

APPEAL BRIEF (37 C.F.R. section 41.37)

This brief is in furtherance of the Appeal Brief, filed in this case on February 22, 2005. This brief is amended in response to the Notice of Non-Compliant Appeal Brief mailed July 18, 2005, and refiled to comply with the requirements set forth in 37 CFR 41.37.

The fees required for a petition for extension of time under 37 CFR 1.136 for filing this brief and fees therefore, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains these items under the following headings, and in the order set forth below (37 C.F.R. section 41.37(c)):

- I REAL PARTY IN INTEREST
- II RELATED APPEALS AND INTERFERENCES
- III STATUS OF CLAIMS
- IV STATUS OF AMENDMENTS
- V SUMMARY OF CLAIMED SUBJECT MATTER
- VI GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
- VII ARGUMENT
- VIII CLAIMS APPENDIX
- IX EVIDENCE APPENDIX
- X RELATED PROCEEDINGS APPENDIX

The final page of this brief bears the practitioner's signature.

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I REAL PARTY IN INTEREST (37 C.F.R. section 41.37(c)(1)(i))

The real party in interest in this appeal is The Regents of the University of California

II RELATED APPEALS AND INTERFERENCES (37 C.F.R. section 41.37(c)(1)(ii))

There are no other prior or pending appeals, interferences or judicial proceedings known to Appellants, the Appellants' legal representative, or the Assignee which may be related to, directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

II STATUS OF CLAIMS (37 C.F.R. section 41.37(c)(1)(iii))

1. Claims pending and currently on appeal: 1, 3, 5, 8-12, 20-28, and 30.
2. Claims rejected: 1, 3, 5, 8-12, 20-28 and 30
3. Claims allowed: none
4. Claims canceled: 2, 4, 6-7, 13-19 and 29.

IV STATUS OF AMENDMENTS (37 C.F.R. section 41.37(c)(1)(iv))

No amendments have been filed subsequent to final rejection.

V SUMMARY OF CLAIMED SUBJECT MATTER (37 C.F.R. section 41.37(c)(1)(v))

Independent Claim 1 recites a multilayer article comprising a metal substrate and a first layer comprising a glass composition which comprises, 44.2 to 67.7 wt% SiO₂, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na₂O, 2.2 to 6.5 wt% K₂O and 6.0 wt% P₂O₅, wherein the glass composition contains hydroxyapatite particles in an amount of up to 50 wt%. Support for Claim 1 is indicated in the following Table:

Claim 1	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
1. A multilayer article comprising,		
a metal substrate,	Page 8, line 1	Page 2, col 2, 4 th full ¶
a first layer comprising an inner and outer surface, said first layer comprising a glass composition,	Page 7, 1 st full ¶ Page 8, lines 4-6	Page 2, col 2, 4 th full ¶
said glass composition comprising, 44.2 to 67.7 wt% SiO ₂ , 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na ₂ O, 2.2 to 6.5 wt% K ₂ O and 6.0 wt% P ₂ O ₅ ,	Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, Table I
wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.	Page 7, 4 th full ¶ Page 11, line 5 Page 12, lines 8-9 Fig. 2 and page 5, 5 th ¶	Page 2, col 2, 4 th full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

Claim 3 recites the multilayer article of Claim 1 wherein there is a first intermediate layer that has a glass composition as defined in Claim 1 and is located between the substrate and the first layer. Support for Claim 3 is indicated in the following Table:

Claim 3	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
3.The multilayer article of claim 1,		
wherein there is a first intermediate layer having an inner and outer surface, and said first intermediate layer is located between the substrate and first layer,	Page 8, lines 4-6	Page 2, col 2, 4 th full ¶
said first intermediate layer comprising a glass composition as defined in claim 1.	Page 7, 1 st full ¶ Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, col 2, 4 th full ¶ Page 2, Table I

Claim 5 recites the multilayer article of Claim 3, which has a second intermediate layer with a glass composition as defined in Claim 1 and located between the first intermediate layer and the substrate. The hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is between

the first layer and the second intermediate layer. Support for Claim 5 is indicated in the following Table:

Claim 5	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
5. The multilayer article of claim 3,		
wherein there is a second intermediate layer located between the first intermediate layer and the substrate,	Page 8, lines 4-6	Page 2, col 2, 4 th full ¶
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,	Page 7, 1 st full ¶ Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, col 2, 4 th full ¶ Page 2, Table I
wherein the hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.	Page 7, 1 st full ¶ Page 8, last full ¶ Page 11, lines 6-11 Fig. 2 and page 5, 5 th ¶	

Claim 8 recites the multilayer article of Claim 1 with a substrate that is Ti or Ti6Al4V.

Support for Claim 8 is indicated in the following Table:

Claim 8	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
8. The multilayer article of claim 1,		
wherein the substrate is Ti or Ti6Al4V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 st ¶

Claim 9 recites the multilayer article of Claim 3 with a glass composition in the first layer, which comprises about 54.5 wt% SiO₂, about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na₂O, about 4.0 wt% K₂O and about 6.0 wt% P₂O₅ and a glass composition in the first intermediate layer, which comprises about 61.1 wt% SiO₂, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na₂O, about 2.8 wt% K₂O and about 6.0 wt% P₂O₅, and a substrate that is Ti or Ti6Al4V. Support for Claim 9 is indicated in the following Table:

Claim 9	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
9. The multilayer article of claim 3,		
wherein the glass composition in the first layer comprises about 54.5 wt% SiO ₂ , about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na ₂ O, about 4.0 wt% K ₂ O and about 6.0 wt% P ₂ O ₅ ,	Page 7, 1 st full ¶ Page 8, last full ¶ Page 9, Table 1 Page 11, lines 12-18	Page 2, col 2, 1 st full ¶ Page 2, Table I Page 7, col 2
and the glass composition in the first intermediate layer comprises about 61.1 wt% SiO ₂ , about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na ₂ O, about 2.8 wt% K ₂ O and about 6.0 wt% P ₂ O ₅ ,	Page 7, 1 st full ¶ Page 8, last full ¶ Page 9, Table 1 Page 11, lines 12-18	Page 2, col 2, 1 st full ¶ Page 2, Table I Page 7, col 2
and the substrate is Ti or Ti6Al4V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 st ¶

Claim 11 recites the multilayer article of Claim 3 with a glass composition in the first layer and in the first intermediate layer, which comprises about 56.5 wt% SiO₂, about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na₂O, about 3.0 wt% K₂O and about 6.0 wt% P₂O₅. The hydroxyapatite amount in the first layer is 50 wt%, and the substrate is Ti or Ti₆Al₄V.

Support for Claim 11 is indicated in the following Table:

Claim 11	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
11. The multilayer article of claim 3,		
wherein the glass composition in the first layer and the first intermediate layer comprise about 56.5 wt% SiO ₂ , about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na ₂ O, about 3.0 wt% K ₂ O and about 6.0 wt% P ₂ O ₅	Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, col 2, 4 th full ¶ Page 2, Table I
and the hydroxyapatite amount in the first layer is 50 wt%,	Page 7, 4 th full ¶ Page 11, line 5	Page 2, col 2, 4 th full ¶ Page 8, col 1 lines 8-9 Page 14, Table II
and the substrate is Ti or Ti ₆ Al ₄ V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 st ¶

Claim 12 recites the multilayer article of Claim 5 with glass compositions in the first layer, the first intermediate layer and the second intermediate layer each comprising about 61.1 wt% SiO₂, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na₂O, about 2.8 wt% K₂O and about 6.0 wt% P₂O₅. The hydroxyapatite amount in the first layer comprises 50 wt%, and the substrate is Ti or Ti₆Al₄V. Support for Claim 12 is indicated in the following Table:

Claim 12	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
12.The multilayer article of claim 5,		
wherein the glass composition in the first layer, the first intermediate layer and the second intermediate layer each comprise about 61.1 wt% SiO ₂ , about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na ₂ O, about 2.8 wt% K ₂ O and about 6.0 wt% P ₂ O ₅	Page 7, 1 st full ¶ Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, col 2, 4 th full ¶ Page 2 Table I
and the hydroxyapatite amount in the first layer comprises 50 wt%	Page 7, 4 th full ¶ Page 11, line 5	Page 2, col 2, 4 th full ¶ Page 8, col 1 lines 8-9 Page 14, Table II
and the substrate is Ti or Ti ₆ Al ₄ V.	Page 6, line 13 Page 8, line 1	Page 2, line 5 Page 18, col 1, 1 st ¶

Independent Claim 20 recites multilayer article comprising a substrate that is Ti or Ti₆Al₄V, a first layer and n intermediate layers disposed between the first layer and the substrate. The first layer and the n intermediate layers each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles in an amount up to 50 wt%. The glass composition comprises about 44.2 to about 67.7 wt% SiO₂,

about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na₂O, about 2.2 to about 6.5 wt% K₂O and about 6.0 wt% P₂O₅. Support for Claim 20 is indicated in the following Table:

Independent Claim 20	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
20. A multilayer article comprising, a metal substrate comprising Ti or Ti ₆ Al ₄ V, n intermediate layers, where n is an integer, a first layer comprising an inner and outer surface, said n intermediate layers disposed between the metal substrate and the first layer, wherein the n intermediate layers and the first layer each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles (HA), said glass composition comprising, about 44.2 to about 67.7 wt% SiO ₂ , about 10.1 to about 23.4 wt% CaO, about 5.7 to about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na ₂ O, about 2.2 to about 6.5 wt% K ₂ O and about 6.0 wt% P ₂ O ₅ , and wherein said hydroxyapatite particles being present in the glass/hydroxyapatite admixture in an amount of up to 50 wt%.	Page 6, line 13 Page 8, line 1 Page 8, 1 st full ¶ Page 10, line 17 Page 10, line 18 Page 8, 1 st full ¶ Page 10, line 19 Page 7, 1 st full ¶ Page 10, lines 20-22 Page 9, Table 1 Page 7, 4 th full ¶ Page 11, line 5 Fig. 2 and page 5, 5 th ¶	Page 2, line 5 Page 18, col 1, 1 st ¶ Page 2, col 2, 4 th full ¶ Page 2, col 2, 4 th full ¶ Page 2, col 2, 4 th full ¶ Page 2, col 2, 1 st full ¶ Page 2, Table I Page 2, col 2, 4 th full ¶ Page 8, col 1 lines 8-9 Page 14, Table II

Claim 21 recites the multilayer article of Claim 20 with a first layer that has a glass composition with a SiO₂ content between about 53 to about 57 wt%. Support for Claim 21 is indicated in the following Table:

Claim 21	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
21. The multilayer article of claim 20, wherein: the first layer has a glass composition which has a SiO ₂ content between about 53 to about 57 wt%.	Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, Table I

Claim 22 recites the multilayer article of Claim 21, wherein n=2.. Support for Claim 22 is indicated in the following Table:

Claim 22	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
22. The multilayer article of claim 21, wherein n=2.	Page 8, 1 st full ¶	Page 2, col 2, 4 th full ¶ Page 7, col 1 last ¶ – col 2

Claim 23 recites the multilayer article of Claim 1, wherein the first layer has a glass composition with a SiO₂ content between about 53 to about 57 wt%.. Support for Claim 23 is indicated in the following Table:

Claim 23	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
23.The multilayer article of claim 1, wherein:		
the first layer has a glass composition which has a SiO ₂ content between about 53 to about 57 wt%.	Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, Table I

Claim 24 recites the multilayer article of Claim 23 wherein n=2. Support for Claim 24 is indicated in the following Table:

Claim 24	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
24.The multilayer article of claim 23, wherein n=2.	Page 8, 1 st full ¶	Page 2, col 2, 4 th full ¶ Page 7, col 1 last ¶ – col 2

Claim 25 recites the multilayer article of Claim 20 wherein the first layer has a glass composition with a SiO₂ content between about 56 to about 67.7 wt%. Support for Claim 25 is indicated in the following Table:

Claim 24	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
25.The multilayer article of claim 20, wherein:		
the first layer has a glass composition which has a SiO ₂ content between about 56 to about 67.7 wt%.	Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, Table I

Claim 26 recites the multilayer article of Claim 25 wherein n=2. Support for Claim 26 is indicated in the following Table:

Claim 26	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
26.The multilayer article of claim 25, wherein n=2.	Page 8, 1 st full ¶	Page 2, col 2, 4 th full ¶ Page 7, col 1 last ¶ – col 2

Claim 27 recites the multilayer article of Claim 1 wherein the first layer has a glass composition with a SiO₂ content between about 56 to about 67.7 wt%. Support for Claim 27 is indicated in the following Table:

Claim 27	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
27. The multilayer article of claim 1, wherein:		
the first layer has a glass composition which has a SiO ₂ content between about 56 to about 67.7 wt%.	Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, Table I

Claim 28 recites the multilayer article of Claim 27 wherein n=2. Support for Claim 28 is indicated in the following Table:

Claim 28	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
28.The multilayer article of claim 27, wherein n=2.	Page 8, 1 st full ¶	Page 2, col 2, 4 th full ¶ Page 7, col 1 last ¶ – col 2

Claim 30 recites the multilayer article of Claim 3 wherein there is a second intermediate layer located between the first intermediate layer and the substrate. The first layer, first intermediate layer and second intermediate layer all comprising a glass composition as defined in Claim 1, and the SiO₂ concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer. Support for Claim 30 is indicated in the following Table:

Claim 30	Utility 09/845,597 ('597)	Provisional 60/201,556 ('566)
30.The multilayer article of claim 3, wherein there is a second intermediate layer located between the first intermediate layer and the substrate,	Page 8, 1 st full ¶	Page 2, col 2, 4 th full ¶ Page 7, col 1 last ¶ – col 2
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,	Page 9, Table 1	Page 2, col 2, 1 st full ¶ Page 2, Table I
wherein the SiO ₂ concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.	Page 11, lines 12-18	Page 7, col 1 last ¶ – col 2

VI GROUND OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R. section 41.37(c)(1)(vi))

1) Claim for Priority to Provisional Application 60/201,556, filed May 1, 2000

The priority claim has been denied for non-compliance with the conditions for receiving priority as stated in 35 USC 111(b)(1) and the first paragraph of 35 USC 112. In addition, the provisional application is seen not to provide support for the claimed invention.

- a. Claims 1, 3, 5, 8-12 and 20-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published **February 2000**.
- b. Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published **February 2000**, and further in view of “A multilayer approach to fabricate bioactive glass coatings on Ti alloys,” by Gomez-Vega et al, published **June 1999**.

2) Anticipation by “HA-bioactive glass composites...”

Claims 1, 8 and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by the article titled “HA-bioactive glass composites: High temperature reactivity and ‘in-vitro’ behavior” by Pazo, et al., published 1996.

VII ARGUMENT (37 C.F.R. 41.37(c)(1)(vii))

1) Claim for Priority to Provisional Application 60/201,556, ('566), filed May 1, 2000

In the Final Office Action after RCE, mailed February 24, 2002, the Examiner has denied the claim for priority, stating that the provisional application contains a collection of articles which are not seen to provide support for the claimed invention. The Examiner has stated further that the inventive entity of at least one article is not the same as that of the present invention and that the IDS designates three articles as Prior Art which are also included as part of the Provisional Application.

A provisional application for patent shall include, as stated in 35 USC 111(b)(1) & (2):

(A) a specification as prescribed by the first paragraph of section 112 of this title; and

(B) a drawing as prescribed by section 113 of this title.

(2) CLAIM.—A claim, as required by the second through fifth paragraphs of section 112, shall not be required in a provisional application.

and referring to 35 USC 112 Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

and to 35 USC 113 Drawings

The applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented. When the nature of such subject matter admits of illustration by a drawing and the applicant has not furnished such a drawing, the Director may require its submission within a time period of not less than two months from the sending of a notice thereof. Drawings submitted after the filing date of the application may not be used (i) to overcome any insufficiency of the specification due to lack of an enabling disclosure or otherwise inadequate disclosure therein, or (ii) to supplement the original disclosure thereof for the purpose of interpretation of the scope of any claim.

Applicants respectfully traverse this rejection and assert that the provisional application '566 meets the requirements for a provisional application and that the claim for priority should be allowed.

“[F]or the non-provisional utility application to be afforded the priority date of the provisional application, the two applications must share at least one common inventor and the written description of the provisional must adequately support the claims of the non-provisional application. (*New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002))

The specification for provisional application '566 includes the following sections:

- A. Pages 1-11: J. M. Gomez-Vega, Eduardo Saiz and A. P. Tomsia, "Glass-based coatings for titanium implant alloys," J. Biomet.Mater. Res., p. 549-559, (1999).
- B. Pages 12-17: J. M. Gomez-Vega, E. Saiz, A. P. Tomsia, G.W. Marshall, and S.J. Marshall, "A multilayer approach to fabricate bioactive glass coatings on Ti alloys," Biomedical Materials: Drug Delivery, Implants and Tissue Engineering, Mater. Res. Soc. Symp. Proc., p. 349-354, (1999).
- C. Pages 18-24: A. Pazo, E, Saiz, and A. P. Tomsia, "Silicate glass coatings on Ti-based implants," Acta Mater., Vol. 46 (No. 7), p. 2551-2558, (1998).
- D. Pages 25-28: News articles from March 2000 about the research work of Antoni Tomsia and Eduardo Saiz.

Sections A-C are journal articles that provide detailed information about the multilayered glass coatings on Ti and Ti alloys in the instant invention, how they were prepared, and their resulting physical properties. The provisional application provides support for the pending claims. Furthermore, Section A of the provisional application, alone, provides support for the pending claims, as shown in Section V of this brief.

The provisional application '566 and the utility application '597 have been filed with the same list of inventors: J. M. Gomez-Vega, E. Saiz, A. P. Tomsia, G.W. Marshall, and S.J. Marshall. The Examiner asserts that "the inventive entity of at least one article is not the same as that of the present invention." It is difficult to understand what the Examiner means. Is the Examiner saying that because one *author* on a journal article submitted in the provisional application '566 has not been named as an inventor in the utility application '597, Appellants are not entitled to the claim for priority? Appellants point to MPEP section 2137.01 II. which states, "The definition for inventorship can be simply stated: 'The threshold question in determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he is not an inventor.'" The criterion for inclusion as an *author* on a journal article has no direct relation to the criterion for inclusion as an *inventor* on a patent application.

The Examiner has stated that the IDS designates three articles as prior art which are also included as part of the provisional application '566. "The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b)." (37 CFR 1.97(h)) Also, MPEP section 2129 IV. states "Mere listing of a reference in an information disclosure statement is not taken as an admission that the reference is prior art against the claims." Appellants assert

that the inclusion of articles that were part of the provisional application '566 in the IDS of the utility application '597 can, in no way, affect the claim for priority to '566.

Thus, the claim for priority to the provisional application '566 is valid.

1a. Claims 1, 3, 5, 8-12 and 20-28 stand rejected under 35 U.S.C. 102(b) as being anticipated by "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published **February 2000**.

1b. Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over "Glass-hydroxyapatite coatings on titanium-based implants" by Gomez-Vega et al, published February 2000, and further in view of "A multilayer approach to fabricate bioactive glass coatings on Ti alloys," by Gomez-Vega et al, published **June 1999**.

Appellants assert that, as both rejections 1a and 1b are based on references that cannot be considered prior art under 102(b), the rejections are moot and should be withdrawn.

2) Anticipation by "HA-bioactive glass composites..."

Claims 1, 8 and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by the article titled "HA-bioactive glass composites: High temperature reactivity and 'in-vitro' behavior" by Pazo, et al., herein referred to as "Pazo".

Independent Claim 1 recites a multilayer article comprising, a metal substrate and a first layer comprising a glass composition which comprises, 44.2 to 67.7 wt% SiO₂, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na₂O, 2.2 to 6.5 wt% K₂O and 6.0 wt% P₂O₅, wherein the glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.

The Examiner asserts that, "Regarding Claim 1, the reference teaches a multilayered article (see text of page 1733 and Figures 6 and 7) comprising a Ti or Ti alloy substrate (see line 6 of abstract) and a first layer comprising a glass of the claimed composition (see page 1729, first paragraph under "Materials and Methods), further comprising HA in an amount of 25% (up to 50%) (page 1 729, last paragraph)."

The Pazo abstract (including line 6) said, "...In a previous investigation a new MgO-containing BAG has been developed. This glass combines both high bioactivity and excellent adhesion to Ti and Ti alloys." The abstract said that the glass *has excellent adhesion* to Ti and

Ti alloys. The abstract did not describe a multilayered structure with a metal substrate and a first layer comprising a glass composition, as recited in Claim 1.

The text of page 1733 and Figures 6 and 7 in Pazo referred to the results of two experiments. Figure 6 and the text referred to a composite with a 20% BAG and 80% HA composition obtained by hot pressing at 850°C after soaking in SBF (simulated biological fluid) for 30 days. The result, as shown in Figure 6 and described in the text, was a continuous apatite layer on the surface of the composite. Figure 7 referred to an A-3 glass/coarse HA sample fired at 850°C for 10 minutes after 48 days soaking in SBF. Preparation of this sample was further described in paragraph 3 on page 1730 thus, "...A-3 glass plates ... were coated with HA coarse ... grains and fired at 850°C for 1 h." The result, described in Figure 7, was a new amorphous HA coating on the A-3 glass and on the coarse HA grain surfaces. Pazo included a metal substrate, as recited in Claim 1, in none of his samples either before or after soaking in SBF.

Appellants respectfully traverse the rejection and submit that Pazo failed to teach each and every feature of independent Claim 1.

Dependent Claims 8 and 23 each depend from independent Claim 1 and therefore include all the features and limitations thereof. Furthermore, the dependent claims add additional distinguishing features of particular utility. Accordingly, Appellants submit that dependent Claims 8 and 23 are also allowable over Pazo.

VIII CLAIMS APPENDIX (37 C.F.R. section 41.37(c)(1)(viii))

1. A multilayer article comprising,
a metal substrate,
a first layer comprising an inner and outer surface,
said first layer comprising a glass composition,
said glass composition comprising,
44.2 to 67.7 wt% SiO₂, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO, 10.3 to 23.6 wt% Na₂O, 2.2 to 6.5 wt% K₂O and 6.0 wt% P₂O₅,
wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.
3. The multilayer article of claim 1,
wherein there is a first intermediate layer having an inner and outer surface,
and said first intermediate layer is located between the substrate and first layer,
said first intermediate layer comprising a glass composition as defined in claim 1.
5. The multilayer article of claim 3,
wherein there is a second intermediate layer located between the first intermediate layer and the substrate,
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,
wherein the hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.
8. The multilayer article of claim 1,
wherein the substrate is Ti or Ti₆Al₄V.

9. The multilayer article of claim 3,
wherein the glass composition in the first layer comprises about 54.5 wt% SiO₂, about 15 wt% CaO, about 8.5 wt% MgO, about 12.0 wt% Na₂O, about 4.0 wt% K₂O and about 6.0 wt% P₂O₅,
and the glass composition in the first intermediate layer comprises about 61.1 wt% SiO₂, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na₂O, about 2.8 wt% K₂O and about 6.0 wt% P₂O₅,
and the substrate is Ti or Ti6Al4V.
10. The multilayer article of claim 3,
wherein the glass composition in the first layer comprises about 52.7 wt% SiO₂, about 12.6 wt% CaO, about 7.1 wt% MgO, about 17.0 wt% Na₂O, about 4.6 wt% K₂O and about 6.0 wt% P₂O₅,
and the glass composition in the first intermediate layer comprises:
about 56.5 wt% SiO₂, about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na₂O, about 3.0 wt% K₂O and about 6.0 wt% P₂O₅,
and the substrate is Ti or Ti6Al4V.
11. The multilayer article of claim 3,
wherein the glass composition in the first layer and the first intermediate layer comprise about 56.5 wt% SiO₂, about 15 wt% CaO, about 8.5 wt% MgO, about 11.0 wt% Na₂O, about 3.0 wt% K₂O and about 6.0 wt% P₂O₅ and the hydroxyapatite amount in the first layer is 50 wt%,
and the substrate is Ti or Ti6Al4V.
12. The multilayer article of claim 5,
wherein the glass composition in the first layer, the first intermediate layer and the second intermediate layer each comprise about 61.1 wt% SiO₂, about 12.6 wt% CaO, about 7.2 wt% MgO, about 10.3 wt% Na₂O, about 2.8 wt% K₂O and about 6.0 wt% P₂O₅ and the hydroxyapatite amount in the first layer comprises 50 wt%
and the substrate is Ti or Ti6Al4V.

20. A multilayer article comprising,
a metal substrate comprising Ti or Ti6Al4V,
n intermediate layers, where n is an integer,
a first layer comprising an inner and outer surface,
said n intermediate layers disposed between the metal substrate and the first layer,
wherein the n intermediate layers and the first layer each independently comprise a
glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite
particles (HA),
said glass composition comprising,
about 44.2 to about 67.7 wt% SiO₂, about 10.1 to about 23.4 wt% CaO, about 5.7 to
about 13.3 wt% MgO, about 10.3 to about 23.6 wt% Na₂O, about 2.2 to about 6.5 wt%
K₂O and about 6.0 wt% P₂O₅,
and wherein said hydroxyapatite particles being present in the glass/hydroxyapatite
admixture in an amount of up to 50 wt%.
21. The multilayer article of claim 20, wherein:
the first layer has a glass composition which has a SiO₂ content between about 53 to
about 57 wt%.
22. The multilayer article of claim 21, wherein:
n=2.
23. The multilayer article of claim 1, wherein:
the first layer has a glass composition which has a SiO₂ content between about 53 to
about 57 wt%.
24. The multilayer article of claim 23, wherein:
n=2.
25. The multilayer article of claim 20, wherein:
the first layer has a glass composition which has a SiO₂ content between about 56 to
about 67.7 wt%.

26. The multilayer article of claim 25, wherein:

n=2.

27. The multilayer article of claim 1, wherein:

the first layer has a glass composition which has a SiO₂ content between about 56 to about 67.7 wt%.

28. The multilayer article of claim 27, wherein:

n=2.

30. The multilayer article of claim 3,

wherein there is a second intermediate layer located between the first intermediate layer and the substrate,

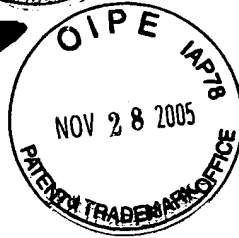
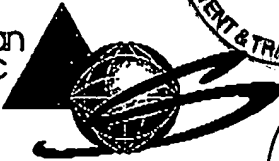
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,

wherein the SiO₂ concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.

IX EVIDENCE APPENDIX (37 C.F.R. section 41.37(c)(1)(ix))

A letter from Greg Geiger, American Ceramic Society Development Editor for books states that the publication of the proceedings of the Bioceramics: Materials and Applications symposium, held at the 101st Annual meeting of The American Ceramic Society occurred in February 2000. The reference “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, relied upon by the Examiner as prior art, was part of this publication. This evidence was submitted to the Examiner on May 2, 2003 and is submitted here on the following page in support of the present appeal brief.

The
American
Ceramic
Society



May 2, 2003

To Whom It May Concern:

This letter is in regard to The American Ceramic Society publication: Bioceramics: Materials and Applications III, Ceramic Transactions, Volume 110, edited by Laurie George, Richard P. Rusin, Gary S. Fischman, and Vic Janas; copyright 2000; ISBN 1-57498-102-1.

This book was based on the proceedings of the Bioceramics: Materials and Applications symposium, held at the 101st Annual Meeting of The American Ceramic Society in Indianapolis, Indiana, April 25-28, 1999. The book was printed in February of 2000 with the first books being mailed to customers on 2/23/2000.

Regards,

Greg Geiger
Development Editor, Books
The American Ceramic Society

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X RELATED PROCEEDINGS APPENDIX (37 C.F.R. section 41.37(c)(1)(x))

There are no known related proceedings.

Respectfully Submitted:

Date: November 23, 2005

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